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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,313	04/09/2002	Sharon May Armitage	1386/5 PCT	7941

7590 08/20/2004
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EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT PAPER NUMBER

1634

DATE MAILED: 08/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,313

Applicant(s)

ARMITAGE ET AL.

Examiner

Jeanine A Goldberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-36 and 38-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-36 and 38-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. This action is in response to the papers filed June 9, 2004.
2. Currently, claims 33-36, 38-58 are pending.
3. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow.
4. Any objections and rejections not reiterated below are hereby withdrawn in view of the amendments to the title and the claims.

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 34-43, 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

B) Claim 34-35 are indefinite over the recitation "suitable for digestion together with said biological sample" because it is unclear whether "sheets of material are digestable with the sample" to form a solution or whether the "sheets of material allow a sample to be digested" or whether the "sheets of material" allow for a sample to be eluted and/or obtained. Further, from the specification, it does not appear that the sheets of material are digested with the biological sample. According to Example 1, a hole is punched through a sample storage device and placed in a tube or well, centrifuged to collect the sub-sample in the bottom of the tube. The supernatant is

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transferred to a tube for amplification and analysis. It is unclear from the example whether the paper or polypropylene film would be digested at these conditions or whether the sample is merely eluted from the storage means. Thus, the metes and bounds of the claimed invention are unclear.

C) Claim 36-43, 47 are indefinite over the recitation "substantially irreversibly adhered together" in Claim 43 because it is unclear what is within the scope of the recitation. The term "substantially irreversibly adhered together" in claim 43 is a relative term which renders the claim indefinite. The term "substantially irreversibly adhered together" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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6. Claims 33-35, 40-41, 43, 45-46, 48-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Perlman (US Pat. 5,858,770, January 12, 1999).

The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525,1528 (Fed. Cir. 1990) (see MPEP, 2114). A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Perlman teaches a cell culture plate with oxygen and carbon dioxide-permeable waterproof sealing membrane. Perlman teaches a cell culture plate which is covered and sealed with a waterproof adhesive sealing membrane (abstract). Perlman teaches that the prior art uses a cover which may be a gas-impermeable adhesive polyester, polypropylene or polyethylene plastic sealing film (col. 1, lines 50-51)(limitations of Claim 33, 53-54).

With respect to the invention of Perlman, Perlman teaches improving the multiwell culture plate by providing a gas-permeable, leak-proof, and adhesive membrane for sealing such plates. Perlman teaches that membranes are generally thin, and it does not peel off any of the culture plates tested (col. 2, lines 13-14). The membranes of Perlman are polyester-polyurethane or polyether-polyurethane which

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adhere to the culture plate to exclude contaminants from the wells of the plate (col. 3, lines 20-30)(limitations of Claim 53). The removable release sheet may be attached to the lower surface or adhesive coating on the facestock to protect the adhesive from contaminating substances prior to use (col. 4, lines 55-60). As shown in Figure 1, a cell culture plate is assembled from a sterile sheet assembly and a cell culture plate (limitations of Claim 33-35, 55-57). The sheet assembly consist of three layers, an upper layer which serves as a carrier sheet, a middle layer which functions as the breathable adhesive sealing membrane and a lower layer which functions as a release paper sheet to protect the adhesive coating (col. 7, lines 5-12). The wells are suitable for solution digestion of the biological sample with phenol/chloroform or alkali solution (limitations of Claim 44, 48-49). The claims do not particular require the solution be present in the device, thus, the instant device is suitable for using such solutions. These limitations do not materially change the structure of the claimed storage device.

With respect to Claims 46, 50-52, the claims are directed to particular biological samples. It is noted that the claims do not require a biological sample. Since the wells are suitable for use with an animal or plant, the biological sample may be animal or plant. Thus, these limitations fail to distinguish the device from the structure of the prior art device.

Since, Perlman teaches every limitation of the claims, Perlman anticipates the claimed invention.

Response to Arguments

The response traverses the rejection. The response asserts Perlman fails to teach every limitation of the instant claims. Specifically, the response asserts that Perlman does not appear to teach or suggest a storage device comprising a "storage structure being suitable for at least partial digestion together with said biological sample for subsequent analysis" (page 11 of response filed June 9, 2004). The response cites various teachings from Perlman to infer that the membrane of Perlman is not configured to be digested with the cells. It appears that applicants are reading the claims more narrowly than the examiner. The examiner is interpreting the claims to merely require that digestion may take place in the presence of the device. Therefore, this argument has been reviewed but is not convincing because the storage device of Perlman is a microwell plate comprising a membrane cover. The device is tamper-evident and is configured to store a biological sample. The microwell plate is suitable for allowing digestion of a biological sample with the plate. It appears as though applicant may be trying to argue that the storage structure is also digested, however, the claim does not specifically require such a limitation. The claims requires a storage structure which is suitable for at least partial digestion with the biological sample, which encompasses a structure which allows the biological sample to be digested while in the presence of the structure. There is no doubt that a microwell plate with biological sample may allow for partial digestion of the biological sample.

Thus for the reasons above and those already of record, the rejection is maintained.

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7. Claims 33-36, 38-39, 41-47 and Newly added Claims 48-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Hiersteiner (US Pat. 3,733,025, May 1973).

The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525,1528 (Fed. Cir. 1990) (see MPEP, 2114). A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Hiersteiner teaches an easy opening envelope, a device, which comprises a tamper-evident storage means for storing a sample. As seen in Figure 1, the envelope comprises a backing sheet which is releasably secured to the surface of the cover sheet facing the base sheet (Figure 1, number 22)(limitations of Claim 41). An adhesive strip is applied over the exposed surface which is releasable type (col. 2, lines 8-10). The adhesive strip is permanently affixed to the cover sheet (limitations of Claim 39, 47). The envelope also comprises a base sheet where the biological sample may be placed and a cover sheet which is secured to the base sheet through a fold line (see Figure 1, number 19)(limitations of Claim 37, 43). To open the envelope the cover may be torn from the base sheet using number 31, with tear perforations which would illustrate that the product had been tampered with, i.e. tamper evident. The sheets are substantially

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irreversibly adhered together (limitations of Claim 35). Hiersteiner teaches that the envelope is made of paper (col. 2, lines 19-20)(limitations of Claim 38). Paper is suitable for digestion (limitations of Claim 34). Since the envelope is used for mailing items in the pocket, addresses and stamps are placed on the reverse side of the base sheet (limitation of Claim 36).

With respect to Claims 46, 50-52, the claims are directed to particular biological samples. It is noted that the claims do not require a biological sample. Since the envelope is suitable for use with an animal or plant, the biological sample may be animal or plant. Thus, these limitations fail to distinguish the device from the structure of the prior art device. Since, Hiersteiner teaches every limitation of the claims, Hiersteiner anticipates the claimed invention.

Response to Arguments

The response traverses the rejection. The response asserts Hiersteiner fails to teach every limitation of the instant claims. Specifically, the response asserts that Hiersteiner does not appear to teach or suggest a storage device comprising a "storage structure being suitable for at least partial digestion together with said biological sample for subsequent analysis" (page 13 of response filed June 9, 2004). The response further asserts that Hiersteiner does not mention a biological sample. This argument has been reviewed but is not convincing because the storage device of Hiersteiner is an envelope which is suitable for storing a biological sample. In response to applicant's argument that Hiersteiner does not teach the envelop is configured to store a biological sample, a recitation of the intended use of the claimed invention must result in a

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structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

The claim does not require that there is a biological sample within the device. There are no reasons presented on the record or any scientific analysis as to why the envelope of Hiersteiner would not be suitable for storing a biological sample. For example, hair, FTA cards, microscope slides, etc would fit within the envelope such that the envelope is configured for storing the sample. Further, the envelope is made of material that is suitable and would allow subsequent digestion.

8. Claims 33-35, 41, 43, 45-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Bender (US Pat 3,965,888, June 1976).

The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP, 2114). A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the

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prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Bender teaches a specimen collector and holder. The specimen holder includes a transparent adhesive coated foldable segment that is used to collect the specimen and retain the back-folded segment for visual examination (abstract). As seen in Figure 1, the collector contains a base, a cover and a releasable adhered backing sheet (limitations of Claim 33-34, 43, 47). After a sample is collected, the adhesive segment is folded-back for visualization. The collector of Bender allows specimen transfers and the use of glass slides are eliminated while the specimen can be conveniently examined without contamination. The transparent plastic material segment is provided with a fold-line located in such manner that the adhesive area may be folded back upon the main body of the swab itself so that the specimen can be examined through the transparent swab (col. 1, lines 55-65). Prior to use of the swab, the cover sheet (number 18) is removed and the adhesive is then applied to a body surface (col. 3, lines 5-10)(limitations of Claim 35, 41). After collection of the specimen by its sticking to the adhesive the end is bent back upon itself so that the adhesive segment is located against the transparent flat area of the swab (col. 3, lines 10-15). The specimen can then be examined through the transparent swab while being protected (col. 3, lines 15-20).

With respect to Claims 46, 50-52, the claims are directed to particular biological samples. It is noted that the claims do not require a biological sample. Thus, these limitations fail to distinguish the device from the structure of the prior art device. Since

Bender teaches each limitation of the instant claims, Bender anticipates the instant invention.

Response to Arguments

The response traverses the rejection. The response asserts Bender fails to teach every limitation of the instant claims. Specifically, the response asserts that Bender does not appear to teach or suggest a storage device comprising a "storage structure being suitable for at least partial digestion together with said biological sample for subsequent analysis" (page 14 of response filed June 9, 2004). The response further asserts that Bender does not teach that the specimen holder is digestible. The claims does not appear to require that the specimen holder is digestible with any particular material. The claim requires that the structure is suitable for partial digestion with biological sample which has been broadly interpreted to mean. Moreover, the claim is drawn to a product claim, thus, the recitation for subsequent analysis does not require any method steps. Moreover, visual inspection would be encompassed by subsequent analysis.

The claim does not require that there is a biological sample within the device.

9. Claims 33-36, 38-39, 42-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Draper (US Pat. 6,007,104, December 1999).

The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is,

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not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525,1528 (Fed. Cir. 1990) (see MPEP, 2114). A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Draper teaches a medical device and form for collecting samples. The device, as seen in Figure 1-3 illustrates a multilayer device for collecting laboratory samples. On the left side of the device, samples are obtained and on the right side of the device, information including individual, insurance information is included along with bar codes. The separation line divides the form portion from the medical device portion. A securement sheet has a pressure sensitive adhesive which secures the medical device to the substrate (col. 2, lines 25-30). The device, as seen in Figure 3, contains a base sheet, a cover sheet with an adhesive (limitations of Claim 33-35, 37, 43). The substrate is a heavyweight paper or paperboard (col. 3, lines 15-20). The form portion contains biographical data, instructions, bar codes and other identification material (col. 3, lines 15-20). A blood application sheet is secured to the front of the substrate by a securement sheet. The securement sheet includes a pressure sensitive adhesive (col. 4, lines 15-25)(limitations of Claim 39). The back cover sheet is preferably a flexible sheet of water, oil and grease resistant paper (col. 4, lines 55-60)(limitations of Claim 38).

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With respect to Claims 46, 50-52, the claims are directed to particular biological samples. It is noted that the claims do not require a biological sample. Thus, these limitations fail to distinguish the device from the structure of the prior art device. Since Draper teaches every limitation of the instant claims, Draper anticipates the claimed invention.

Response to Arguments

The response traverses the rejection. The response asserts Draper fails to teach every limitation of the instant claims. Specifically, the response asserts that Draper does not appear to teach or suggest a storage device comprising a "storage structure being suitable for at least partial digestion together with said biological sample for subsequent analysis" (page 15 of response filed June 9, 2004). The response further asserts that Draper does not teach that the specimen holder is digestible. The claims do not appear to require that the specimen holder is digestible with any particular material. The claim requires that the structure is suitable for partial digestion with biological sample which has been broadly interpreted to mean. Moreover, the claim is drawn to a product claim, thus, the recitation for subsequent analysis does not require any method steps. Moreover, visual inspection would be encompassed by subsequent analysis. The claim does not require that there is a biological sample within the device. Thus for the reasons above, and those already of record, Draper anticipates the claimed invention.

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Conclusion

10. No claims allowable over the art.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571) 272-0782.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jeanine Goldberg

Patent Examiner

August 10, 2004